



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Meeting of the Secretary's Advisory Committee on Human Research Protections**

**AGENCY:** Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** Pursuant to section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP, the full meeting agenda, and instructions for linking to public access will be posted on the SACHRP website at <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>.

**DATES:** The meeting will be held on Wednesday, March 22, 2023 from 11:00 a.m. until 5:00 p.m., and Thursday, March 23, 2023, from 11:00 a.m. until 5:00 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted on the SACHRP web site as this information becomes available.

**ADDRESSES:** This meeting will be held via webcast. Members of the public may also attend the meeting via webcast. Instructions for attending via webcast will be posted at least one week prior to the meeting at <https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html>.

**FOR FUTHER INFORMATION CONTACT:** Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240-453-8141; fax: 240-453-6909; e-mail address: [SACHRP@hhs.gov](mailto:SACHRP@hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the authority of 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended, SACHRP was established to provide

expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 11:00 a.m., on Wednesday, March 22, 2023, followed by opening remarks from Julie Kaneshiro, Acting Director of OHRP and Dr. Douglas Diekema, SACHRP Chair. The meeting will begin with an overview of the recently published GAO report #GAO-23-104721, Institutional Review Boards: Actions Needed to Improve Federal Oversight and Examine Effectiveness, followed by a panel of expert speakers addressing the topic of defining stakeholders and evaluating HRPP/IRB quality and effectiveness. SACHRP will subsequently discuss recommendations related to the report's recommendation #4.

A second agenda topic will be introduced and discussed at SACHRP in the afternoon, the FDA draft guidance on Ethical Considerations for Clinical Investigations of Medical Products Involving Children Guidance for Industry, Sponsors, and IRBs.

Discussion of both topics will continue on March 23<sup>rd</sup>. Other topics may be added; for the full and updated meeting agenda, see <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>. The meeting will adjourn by 5:00 p.m. March 23, 2022.

Time will be allotted for public comment on both days of the meeting. The public may submit written public comment in advance to [SACHRP@hhs.gov](mailto:SACHRP@hhs.gov) no later than midnight

March 20th, 2023, ET. Written comments will be shared with SACHRP members and may read aloud during the meeting. Comments which are read aloud are limited to three minutes each. Public comment must be relevant to topics being addressed by the SACHRP.

**Dated:** February 23, 2023.

**Julia G. Gorey,**

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